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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,696	06/26/2003	Shane Sterling	2306-1-5	9640
996	7590	05/18/2006	EXAMINER	
GRAYBEAL, JACKSON, HALEY LLP			ALI, SHUMAYA B	
155 - 108TH AVENUE NE			ART UNIT	
SUITE 350			PAPER NUMBER	
BELLEVUE, WA 98004-5901			3743	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/608,696	Applicant(s) STERLING, SHANE	
	Examiner Shumaya B. Ali	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/27/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18, 19 and 21-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-19, 21-54 is/are rejected.
- 7) ☒ Claim(s) 17 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/26/06 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>detailed action</u> . |

Response to Arguments

1. Applicant has filed terminal disclaimer to overcome double patenting rejection, however in view of the new ground(s) of rejection claims 1-16, 18-19, 21-54 stands unpatentable

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 17-20, 39, are rejected under 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As to claim 7, 48 it is unclear from the specification how the “radial axis” is defined according to applicant (note the objection to the specification below). As to claim 17-19, the structure recited in claims 17-19 are unclear. Note that claims 17-19 appears to use terms to indicate structures which do not have proper support in the specification, (note that in the specification, the 1st, 2nd, and 3rd shells and the 1st, 2nd, cam slots refer to shells or cam slots of the lateral hinge; the 4th, 5th, 6th shells and the 3rd, 4th cam slots refer to the shells and cam slots of the medial hinge; the 1st extension are 35,36; the 2nd extensions are 33,34, the 3rd extensions are 55, 56; the 4th extension are 53, 54) for example, in claim 17, it appears that “said third shell comprising...and said fourth shell comprising...” should be “said fourth shell comprising.. and fifth shell comprising..” As to claim 20, it is unclear according to the specification, how the “first and second radius” is defined (note the objection to the specification below).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-16, 20-22, 38-51, 53, and 54 are anticipated by Bleau et al (US Patent No. 5,792,086).** As to claims 1, 39, 43 Bleau et al disclose a knee brace (see figure 1, knee orthosis 1) with a thigh engaging member (10), a calf engaging member (20), and one or more hinges (30 and/or 40) selected from a hinge lateral (30) to the wearer's knee connecting said thigh engaging member to said calf engaging member, or a hinge medial (40) to the wearer's knee connecting said thigh engaging member to said calf engaging member, as to wherein said knee brace prescribes asymmetric.....a femur and a tibia during flexion and extension of a wearer's leg (note that the statement is only a functional statement without any structure limitation to support the recited function, and therefore is not given any weight) As to claim, "rigid" is a relative term, a material might be "rigid" to one person but might be semi-rigid" or "not rigid" to another, and note that thigh and calf engaging members of Bleau et al are made of injection molded plastic. As to claims 2, 40, note that these claims are only a functional statement without any structure limitation to support the recited function, and therefore are not given any weight. As to claims 4, 11-16, 38, 44-45, 51, and 54 Bleau et al disclose an upper lateral hinge linkage (72) forming said rigid connection between said thigh engaging member and said lateral hinge; a

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lower lateral hinge linkage (73) forming said rigid connection between said calf engaging member and said lateral hinge, and upper medial hinge linkage (70) forming said rigid connection between said thigh engaging member and said medial hinge, a lower medial hinge (71) forming said rigid connection between said calf engaging member and said medial hinge.

As to claims 5,6,46,47 note that a side of each of the cam follower pins of Bleau et al is shaped to track a path parallel to said of each of the cams lots in which the pin is engaged. As to claims 7,48 since the shells of Bleau et al are spherical, and it appear that each of the pins of Bleau et al is fixed to the shell such that center longitudinal axis and the side of the pin are perpendicular to the inside surface of the shell, therefore its side appears to form an angle with a radial axis of the spherical shell of Bleau et al. As to claims 8,49 note that Bleau et al appears to teach an angle of at least 0 degree or more. As to claims 9, 10, 50 note the extension stop members in figure 3 of Bleau et al. As to claims 15 and 53, Bleau et al disclose wherein hinge is a lateral or medial hinge (fig.1) having a variable axis of rotation and comprising a first shell, a second shell, and a third shell (shells are considered 31 and 41) in the shape of a segment of a sphere (as seen in fig.1), said first and third shells being concentric and fastened parallel to each other to form an opening (see fig.1), said first and third shells being fastened to one of said lateral portion of said thigh engaging member (21), and said calf engaging member (11), said second shell having a first end designed to be inserted into said opening and a second end fastened to the other of said lateral portion of said thigh engaging member and said calf engaging member (as seen in fig.1) said first and third shells rotatably engaged to said second shell by said plurality of cam follower pins (90, see figs. 3 and 5) and said plurality of cam slots (37,47,38,34,33,42,43 in fig.1), and note that the last paragraph of claim 15 is only a functional statement. As to claim 21, Bleau et

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al disclose wherein said first radius is in a range form approximately 2.5 inches to 3.5 inches (see fig.1), as to claim 22, Bleau et al disclose wherein said second radius is a range form approximately 1.5 inches to 2.5 inches (see fig.1). As to claims 42 and 43, Bleau et al disclose said unilateral hinge is a lateral hinge (fig.1), and medial hinge (fig.1)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 18 and 19 are unpatentable over Bleau et al (US Patent No. 5,792,086) in view of Bledsoe (US Patent No. 4,46,751).** Bleau et al shows every claimed feature of claims 18 and 19 except for additional extensions for the lateral outside shell and the medial outside shell. However, Bledsoe teaches these additional extensions. In view of Bledsoe, it would have been obvious to an ordinary skill in the art at the time the invention was made to provide the device of Bleau et al with additional extensions for the lateral outside shell and the medial outside shell for the purpose of connecting the shells. Also, note that given the teachings of Bleau et al in view of Bledsoe for the extensions for the lateral inside shell and medial inside

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shell, it would have been obvious to an ordinary skill in the art at the time the invention was made to provide additional extensions for the lateral outside shell and the medial outside shell to connect the shells. The provision of additional extensions for the lateral outside shell and the medial outside shell is well known in the art, and is only a matter of obvious engineering design choice, and therefore is not patentable over prior art.

5. **Claims 23-28 are unpatentable over Bleau et al in view of Tailor et al (US Patent no. 5,277,698), or Brooks et al (US Patent no. 4,475,543), or Cadoret (US Patent no. 5,119,805). As to claims 23,24, 26, and 27,** note that Tailor et al teaches the recited limitation for braces. In view of teachings of Tailor et al, it would have been obvious to an ordinary skill in the art at the time the invention was made to use this material for the brace of Bleau et al for the purposes of providing high flexural and torsion strength. **As to claim 25,** note that the use of aluminum for brace is well known in the art, and therefore is not patentable over prior art. **As to claim 28,** note Brooks et al and Cadoret each shows a brace with a semi-elliptical cross section. In view of the teachings of Brooks et al or Cadoret, it would have been obvious to one of ordinary skills in the art at the time the invention was made to provide the brace of Bleau et al with a semi-elliptical cross section. Note that the provision of padding material for braces is very well known in the art, and note that the shape of the cross section of the brace is only a matter of obvious engineering design choice, and therefore is not patentable over prior art.

Claims 15 and 52 are unpatentable over Bleau et al in view of Taylor (US Patent no. 5,797,864). Bleau et al teach claimed features as applied for claims 5 and 39 above except for a dynamic force strap attaching said thigh engaging member and said calf engaging member to the

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wearer's leg, as to "wherein force is transmitted to a wearer's thigh,.... Symptoms of osteoarthritis in a wearer's knee" is considered recitation of intended use, therefore is not given patentable weight, however Taylor teaches a force directing strap used with an orthopedic hinge brace (see fig. 1, strap 28). Therefore, it would have been obvious to one of ordinary skills in the art at the time of the invention to add a force-directing strap to the invention of Bleau et al in view of Taylor for the purposes of applying lateral force to the knee (see Taylor col.3 lines 47-50)

Allowable Subject Matter

6. Claims 17 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the elliptical cross section as described in the specification (page 19) and claim 28. Any structural detail that is essential for a proper understanding of the disclosed correction or corrected drawings are required in reply to the office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

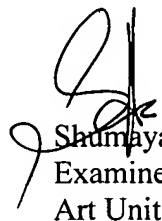
Specification

The disclosure is objected to because of the following reasons: from the specification, it is unclear how the radial axis is defined or measured according to applicant (from what point of or from the shell to what point of or from the shell?) also, it is unclear how the first or second radius is defined or measured according to applicant (from what point of or from the shell to what point of or from the shell?). Clarification is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-F 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 5/15/06
Shumaya B Ali
Examiner
Art Unit 3743


Henry Bennett
Supervisory Patent Examiner
Group 3700